IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ELI LILLY AND COMPANY and THE TRUSTEES OF PRINCETON UNIVERSITY,	)	
Plaintiffs,	)	
v.	)	C. A. No. _____
TEVA PARENTERAL MEDICINES, INC.,	)	
Defendant.	)	

COMPLAINT

Plaintiffs Eli Lilly and Company and The Trustees of Princeton University (collectively "Plaintiffs"), by their attorneys, for their Complaint, allege as follows:

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the filing by defendant Teva Parenteral Medicines, Inc. ("Teva") of an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of ALIMTA® prior to the expiration of U.S. Patent No. 5,344,932.

PARTIES

2. Plaintiff Eli Lilly and Company ("Lilly") is a corporation organized and existing under the laws of the State of Indiana, having its corporate offices and principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285.

3. Plaintiff The Trustees of Princeton University ("Princeton") is a not-for-profit educational institution organized and existing under the laws of the State of New Jersey, having a place of business at One Nassau Hall, Princeton, New Jersey 08540.

4. Upon information and belief, defendant Teva is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 19 Hughes, Irvine, California 92618.

JURISDICTION AND VENUE

5. Jurisdiction and venue are proper in this district pursuant to 28 U.S.C. §§ 1331, 1338(a), 1391, and 1400(b). Teva is subject to personal jurisdiction in Delaware because, among other things, Teva is a resident and citizen of the State of Delaware and has submitted itself to the jurisdiction of courts in Delaware by virtue of its incorporation under Delaware law.

BACKGROUND

6. ALIMTA® is a chemotherapy agent used for the treatment of various types of cancer. ALIMTA® is indicated (in combination with cisplatin) for the treatment of patients with malignant pleural mesothelioma and is also indicated as a single-agent for the treatment of patients with locally advanced or metastatic non-small cell lung cancer after prior chemotherapy.

7. Lilly sells ALIMTA® in the United States pursuant to a New Drug Application that has been approved by the FDA.

COUNT I – U.S. PATENT NO. 5,344,932

8. Plaintiffs incorporate each of the preceding paragraphs 1-7 as if fully set forth herein.

9. United States Patent No. 5,344,932 ("the '932 patent"), entitled "N-(pyrrolo(2,3-d)pyrimidin-3-ylacyl)-Glutamic Acid Derivatives" (Exhibit A hereto), was duly and legally issued on September 6, 1994 to Princeton, as assignee of Edward C. Taylor.

10. Princeton owns the '932 patent. Princeton will be substantially and irreparably damaged by infringement of the '932 patent.

11. Lilly has been granted an exclusive license under the '932 patent. Lilly will be substantially and irreparably damaged by infringement of the '932 patent.

12. ALIMTA® is covered by one or more claims of the '932 patent, and the '932 patent has been listed in connection with that drug product in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*.

13. By letter dated April 24, 2008 (the "Notice Letter"), Teva notified Lilly and Princeton that Teva had submitted to the FDA an ANDA, No. 90-352, for Teva's Pemetrexed Disodium for Injection, Eq. 500 mg Base/Vial, a drug product that is a generic version of ALIMTA® ("Teva's ANDA Product"). The purpose of the ANDA was to obtain approval under the Federal Food, Drug, and Cosmetic Act ("FDCA") to engage in the commercial manufacture, use, offer for sale, and/or sale of Teva's ANDA Product prior to the expiration of, *inter alia*, the '932 patent.

14. In the Notice Letter, Teva also notified Lilly and Princeton that, as part of its ANDA, Teva had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to, *inter alia*, the '932 patent. Upon information and belief, Teva submitted ANDA No. 90-352 to the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '932 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, or sale of Teva's ANDA Product.

15. Teva's ANDA Product is covered by one or more claims of the '932 patent.

16. Teva has knowledge of the '932 patent.

17. Teva's filing of ANDA No. 90-352 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Teva's ANDA Product before the expiration of the '932 patent is an act of infringement of the '932 patent.

18. The manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva's ANDA Product would infringe one or more claims of '932 patent.

19. Upon information and belief, Teva will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva's ANDA Product immediately and imminently upon approval of ANDA No. 90-352.

20. Upon information and belief, use of Teva's ANDA Product in accordance with and as directed by Teva's proposed labeling for that product would infringe one or more claims of the '932 patent.

21. Upon information and belief, Teva will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 90-352.

22. Upon information and belief, Teva plans and intends to, and will, actively induce infringement of the '932 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

23. Upon information and belief, Teva knows that Teva's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '932 patent, and that Teva's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Teva plans and intends to, and will, contribute to infringement of the '932 patent immediately and imminently upon approval of ANDA No. 90-

352.

24. The foregoing actions by Teva constitute and/or will constitute infringement of the '932 patent, active inducement of infringement of the '932 patent, and contribution to the infringement by others of the '932 patent.

25. Upon information and belief, Teva acted without a reasonable basis for believing that it would not be liable for infringing the '932 patent, actively inducing infringement of the '932 patent, and contributing to the infringement by others of the '932 patent.

26. Unless Teva is enjoined from infringing the '932 patent, actively inducing infringement of the '932 patent, and contributing to the infringement by others of the '932 patent, Lilly and Princeton will suffer irreparable injury. Lilly and Princeton have no adequate remedy at law.

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that Teva has infringed the '932 patent;

(b) A judgment ordering that the effective date of any FDA approval for Teva to make, use, offer for sale, sell, market, distribute, or import Teva's ANDA Product, or any product or compound that infringes the '932 patent, be not earlier than the expiration date of the '932 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining Teva, and all persons acting in concert with Teva, from making, using, selling, offering for sale, marketing, distributing, or importing Teva's ANDA Product, or any product or compound that infringes the '932 patent, or the inducement of or the contribution to any of the foregoing, prior to the expiration date of the '932 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.